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10/786,681	02/25/2004	Shanta Modak	A34446-A-PCT-USA-AA	3011
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EXAMINER SAMALA, JAGADISHWAR RAO				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

10/786,681

Applicant(s)

MODAK ET AL.

Examiner

JAGADISHWAR R. SAMALA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/02)
- Paper No(s)/Mail Date 08/27/2009
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments and Remarks filed on 08/27/2009.

- Claims 1 and 2 have been amended.
- Claims 1-4 are pending in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/27/2009 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al (US 5,965,610) in view of Beilfuss et al (US 5,516,510) and Osborne et al (US 5,906,808) **are withdrawn** in view of Applicant's Amendments to claims.

However, upon further consideration a new ground(s) of rejection as prepared as follow.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz et al (US 2003/0211066) in view of Bumier et al (US 5,736,574), Modak et al (US 5,985,918 herein after '918) and Modak et al (US 5,965,610 herein after '610).

Applicant's claims are drawn to an antimicrobial hydroalcoholic composition comprising: antimicrobial agents, octoxyglycerin, a quaternary ammonium compound, wherein the octoxyglycerin and quaternary ammonium compound are present in amounts which exhibit antimicrobial synergy, first and second zinc compounds, wherein the antimicrobial composition is effective in inhibiting gram(+) and gram (-) bacteria.

Scholz teaches a stable hydroalcoholic composition comprising antimicrobial agents such as iodine, chlorhexidine digluconate (0.05-5%) triclosan, surfactants and a quaternary compounds (abstract and 0155-0157). The composition includes emulsifier such as wax emulsifiers and metal salts such as zinc acetate, zinc oxide (0142 and 0160). Additional disclosure includes that compositions are useful as products for skin disinfection such as presurgical hand preps, patient preps, and lotions and have a very nice feel after both single and multiple applications (0009).

Scholz fails to teach octoxyglycerin, first and second zinc compounds and benzalkonium chloride therein the composition.

Burnier teaches combinatorial antimicrobial immixtures comprising N-n-octanoylglycine and an antimicrobial synergistically effective amount octoxyglycerin which are well suited for formulations in a wide variety of pharmaceutical and cosmetic compositions (abstract and Examples 1 and 2). The composition preferably comprises from 0.01% to 6% by weight of glyceryl monoalkyl ether (would read on octoxyglycerin) to the total weight of the composition (col. 3 lines 45-48). Additional disclosure includes that combinatory immixture of antimicrobial activity, and glyceryl monoalkyl ether, manifests a synergistic effect with regard to the antimicrobial activity of the combination (col. 1 line 40-46).

Modak ('918) teaches a topical compositions comprising about 0.1-15% by weight of zinc stearate and about 0.1 -1% by weight of zinc salicylate (claim 1). Additional zinc salts includes zinc gluconate and zinc acetate (Table A and B). Additional disclosure includes that these zinc salts act as anti-irritants by a dual mode of action: (1) they provide sustained low levels of zinc ions on the skin surface which can inactivate existing and invading irritants; and (2) because of its low ionization property, the zinc stabilizes the anionic moiety of the salts and prologs their retention on the skin surface where they form a barrier matrix. This matrix prevents the irritant from contacting the skin surface (col.2 lines 1-7).

Modak discloses a composition comprising an anti-microbial agent in an amount of from about 0.5 % to about 5% (col. 8 lines 50-55) and an anti- binding substance

(2%), which substantially prevents the irritant-inactivating agent from binding to the surface (e.g. soluble zinc compounds). The composition includes anti-microbial agents includes such as iodine, benzalkonium chloride, phenoxyethanol, triclosan, chlorhexidine digluconate (col. 5 lines 2-25), polyethyleneoxide surfactant, quaternary ammonium compounds, cationic substance used to block binding sites on the skin such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate, and zinc salicylate (col. 7 lines 8-24). Additional disclosure includes that composition may further comprises an anti-microbial synergist in addition to the anti-microbial agent and the substance which substantially prevents the anti-microbial agent from binding to the surface (col. 9 lines 7-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate octoxyglycerin into Scholz's composition. The person of ordinary skill in the art would have been motivated to make those modifications because the synergic combination of octoxyglycerin provides the advantage that the compound having antimicrobial activity may be present in lesser amounts in a composition than when it is used alone (col. 3 lines 42-45) and reasonably would have expected success because the antimicrobial combination of this combination is advantageous since it is milder, while at the same time being at least as effective when a cosmetic or dermatological composition comprising this combinatory immixture is topically applied to the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate first and second zinc compounds and benzalkonium

chloride into Scholz's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Modak teaches that addition of small amounts of zinc salicylate to either zinc gluconate or zinc stearate improves the texture of the cream, feel on the hand and relieves pain (col. 4 lines 5-7) and reasonably would have expected success because both Scholz and Modak teaches a antimicrobial composition that can be used in the same field of endeavor such as presurgical scrub replacement, a lotion or other hand preparation such as creams in methods of preventing skin irritation.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jampani et al (US 5,980,925) in view of Cupferman et al (US 6,040,347) and Osborne et al (US 5,906,808) **are withdrawn** in view of Applicant's Amendments to claims.

However, upon further consideration a new ground(s) of rejection as prepared as follow.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz et al (US 2003/0211066) in view of Burnier et al (US 5,736,574), Modak et al (US 5,985,918 herein after '918) and Jampani et al (US 6,022,551).

Applicant's claims are drawn to an antimicrobial hydroalcoholic composition comprising: antimicrobial agents, octoxyglycerin, a quaternary ammonium compound, wherein the octoxyglycerin and quaternary ammonium compound are present in

amounts which exhibit antimicrobial synergy, first and second zinc compounds, wherein the antimicrobial composition is effective in inhibiting gram(+) and gram (-) bacteria.

Scholz teaches a stable hydroalcoholic composition comprising antimicrobial agents such as iodine, chlorhexidine digluconate (0.05-5%) triclosan, surfactants and a quaternary compounds (abstract and 0155-0157). The composition includes emulsifier such as wax emulsifiers and metal salts such as zinc acetate, zinc oxide (0142 and 0160). Additional disclosure includes that compositions are useful as products for skin disinfection such as presurgical hand preps, patient preps, and lotions and have a very nice feel after both single and multiple applications (0009).

Scholz fails to teach octoxyglycerin, first and second zinc compounds and benzalkonium chloride therein the composition.

Burnier teaches combinatorial antimicrobial immixtures comprising N-octanoylglycine and an antimicrobial synergistically effective amount octoxyglycerin which are well suited for formulations in a wide variety of pharmaceutical and cosmetic compositions (abstract and Examples 1 and 2). The composition preferably comprises from 0.01% to 6% by weight of glyceryl monoalkyl ether (would read on octoxyglycerin) to the total weight of the composition (col. 3 lines 45-48). Additional disclosure includes that combinatory immixture of antimicrobial activity, and glyceryl monoalkyl ether, manifests a synergistic effect with regard to the antimicrobial activity of the combination (col. 1 line 40-46).

Modak ('918) teaches a topical compositions comprising about 0.1-15% by weight of zinc stearate and about 0.1 -1% by weight of zinc salicylate (claim 1).

Additional zinc salts includes zinc gluconate and zinc acetate (Table A and B).

Additional disclosure includes that these zinc salts act as anti-irritants by a dual mode of action: (1) they provide sustained low levels of zinc ions on the skin surface which can inactivate existing and invading irritants; and (2) because of its low ionization property, the zinc stabilizes the anionic moiety of the salts and prologs their retention on the skin surface where they form a barrier matrix. This matrix prevents the irritant from contacting the skin surface (col.2 lines 1-7).

Jampani teaches an anti-microbial composition comprising of (a) an antimicrobial selected from the group consisting of triclosan from about 0.1 to 0.5 by weight and (b) benzalkonium chloride from about 0.02 to 1.0 percent by weight (col. 2 lines 11-26). Additional disclosure includes that the composition provides effective protection against a broad spectrum of organism, including gram positive and gram negative for extended period of time (col. 3 lines 48-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate octoxyglycerin into Scholz's composition. The person of ordinary skill in the art would have been motivated to make those modifications because the synergic combination of octoxyglycerin provides the advantage that the compound having antimicrobial activity may be present in lesser amounts in a composition than when it is used alone (col. 3 lines 42-45) and reasonably would have expected success because the antimicrobial combination of this combination is advantageous since it is milder, while at the same time being at least as effective when

a cosmetic or dermatological composition comprising this combinatory immixture is topically applied to the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate first and second zinc compounds chloride into Scholz's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Modak teaches that addition of small amounts of zinc salicylate to either zinc gluconate or zinc stearate improves the texture of the cream, feel on the hand and relieves pain (col. 4 lines 5-7) and reasonably would have expected success because both Scholz and Modak teaches a antimicrobial composition that can be used in the same field of endeavor such as presurgical scrub replacement, a lotion or other hand preparation such as creams in methods of preventing skin irritation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate benzalkonium chloride into Scholz's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Jampani teaches that the composition provides more persistent antimicrobial activity than those other well-known antimicrobial agents and further effective in preventing the appearance of microbes for an extended periods of time, such as greater than three of four hours or more (col. 3 lines 43-57) and reasonably would have expected success because both Scholz and Jampani teaches a antimicrobial composition that can be used in the same field of endeavor such as for

disinfecting surgical scrubs, hand disinfectants and in preoperative preparation of patients.

Double Patenting

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 B2 (herein after '846) abeyance is acknowledged and maintained.

Conclusion

1. No claims are allowed at this time.
2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr